

**Amendments to Drawings:**

The attached sheets of drawings include changes to Figures 1, 6, and 10. These sheets, which include Figures 1-13, replace the original sheets including Figures 1-13.

Figure 1 has been amended to clarify elements 3 and 4 refer to the receptacles, not the arrows.

In Figure 6, element 12 has been changed to element 11'.

In Figure 10, element 2 has been changed to element 12.

**REMARKS/ARGUMENTS**

After this Amendment, Claims 1-21, 23 and 24 are currently pending in this application. Claims 1-18, 21, 23 have been amended. Claim 22 has been canceled. New claim 24 has been added to more distinctly claim subject matter which the Applicants regard as the invention. In the Specification, paragraphs [0031], [0071], [0076], [0080], and [0091], as well as the Abstract, have been amended. Figures 1, 6, and 10 have also been amended. No new matter has been introduced into the application by these amendments.

**Objections to the Specification**

The Examiner objected to the Specification pursuant to MPEP § 608.01(b) noting the Abstract included phrases which can be implied. The Examiner also objected to the Specification due to several informalities. Thus, the Abstract and several paragraphs of the Specification have been amended to address these objections. Consequently, withdrawal of the Specification objections is respectfully requested.

**Objections to the Drawings**

The Examiner objected to the drawings for failure to comply with 37 CFR 1.84(p)(4) and 37 CFR 1.84(p)(4). In the response, the drawings have been amended to address these objections. Replacement sheets including Figures 1-13 are submitted herewith. Consequently, withdrawal of the drawing objections is respectfully requested.

**Claim Rejections - 35 USC § 112**

Claims 1-23 stand rejected under 35 USC § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Specifically, claims 1 and 3 were rejected under 35 USC § 112 due to the inclusion of the terms “can be”, and claim 17 was rejected due to the inclusion of the terms “such as”. Claims 1, 3, and 17 have all been amended to address these rejections. Thus, withdrawal of the section 112 rejection of claims 1, 3, and 17 is respectfully requested.

Furthermore, Applicants note the Examiner has correctly assumed the supply hose, filling material, and elastomer are positively recited limitations the claims.

**Claim Rejections - 35 USC § 102(b)**

Claims 1-8, 17, and 21-23 stand rejected under 35 USC § 102(b) as being anticipated by Barber (U.S. Patent No. 5,236,460). Applicants respectfully traverse this rejection.

Claim 1 is directed to a surgical implant used in procedures for stiffening the vertebral column. The implant has a wedge shaped front end which helps to expand the space between the neighboring vertebral bodies when bringing the implant into position. The implant also has a rear end with an implantation instrument attachment and is adapted for connection to a device used to generate a filling pressure. This implant also has an enclosed hollow body, which has two open, concave receptacles, whose open ends face one another. Furthermore, these two receptacles can be moved toward one another to interlock, such that one receptacle fits within the body of the other receptacle, as depicted in Figure 2. The receptacles can be spread apart from one another to fill the space between neighboring bodies. This spreading action is accomplished by filling the space between the receptacles with an elastomer. As this elastomer is supplied into this space, it fills the space, and then pushes against the receptacle bodies, pushing them away from one another. Also, this implant is insertable into a vertebral disc space. It is not to be used as a complete substitution for an entire vertebral body. This implant device is advantageous because it simplifies surgical implantation and, thus reduces

invasiveness and the risk of surgical trauma. Furthermore, this implant has a wedge shaped front end for spreading vertebral bodies apart before entirely inserting the implant and spreading apart the receptacles. The bean shape also facilitates rotational movement during implementation.

In contrast to the present invention, Barber discloses a tubular shaped prosthesis with telescoping tubular-shaped, flanged bodies. When these bodies are in a retracted position, one of the bodies clearly cannot fit within the other flanged body. In Figure 2 of Barber, body 23 partially fits into body 13. However, no matter how much the bodies are retracted together, the flanged side of body 23 will always stick out; one body is never within the other body.

Thus, for these reasons, Barber clearly does not meet this limitation of amended claim 1.

Claim 5 further recites that the implant is connectable to a hose. Barber fails to teach this limitation. A hose is a flexible tube for conveying a liquid. See "hose." *Dictionary.com Unabridged (v 1.1)*. Random House, Inc. Figures 4-6 of Barber only show a prosthesis connected to a rigid, cylindrical, injecting tool 55, not a flexible hose. There is absolutely no teaching in Barber that its prosthesis is connected to a hose, or flexible tube, at any point. Thus, absent this express teaching, Barber clearly fails to teach this limitation of claim 5.

Amended claim 21 requires the base and cover plates are slightly arched or vaulted with respect to one another. In contrast, the base and cover plates of Barber are completely flat and not arched. Thus, absent this express teaching, Barber fails to meet this limitation of amended claim 21.

Claims 2-8, 17, and 21-23 are allowable over the cited prior art due to the reasons discussed above, as well as due to their dependency upon amended claim 1, which Applicant believes is allowable over the cited prior art of record.

Based on the arguments presented above, withdrawal of the rejection of claims 1-8, 17, and 21-23 under 35 USC § 102(b) is respectfully requested.

**Claim Rejections - 35 USC § 103(a)**

Claims 9-10 stand rejected under 35 USC § 103(a) as being obvious in view of the combination of Barber (U.S. Patent No. 5,236,460) in view of Strnad (U.S. Patent No. 6,296,665). Applicants respectfully traverse this rejection.

Claim 9 is directed to the implant with receptacles, as recited in claim 1, where the receptacles are adjustable between retracted and spaced apart positions with respect to one another. This adjustable movement is limited to a certain, specific area, so the receptacles cannot entirely spread apart from one another, and thus the receptacles will always somewhat overlap when they are in the second, spaced apart position. In addition, claim 10 is directed to this implant recited in

claim 1, where one receptacle has a screw inserted into its side, and the other receptacle has a slit, which accommodates this screw. The screw slides back and forth along the length of this slit as the receptacles are retracted and spread apart from one another. However, this slit is not open-ended. Once the screw slides along the slit and reaches the closed end, it will no longer be able to move. Since the screw is attached to one of the receptacles, when the screw can no longer move, neither can the receptacle to which it is attached. Thus, the screw and slit combination only permits a specific, limited range of movement. Furthermore, this screw provides a strong, secure means to block the receptacles from spreading apart and disengaging from one another.

In contrast to the present invention, Barber teaches the prosthesis, as discussed above and, as the Office Action admits, fails to teach the adjusting movement between the bodies is limited to any specific area. Thus, Barber alone, does not meet this limitation of claim 9.

Strnad teaches a device for spinal fixation with a retractable core, a pair of platform members that extend radially along this core, and a slit and pin combination. However, Strnad fails to address the above-noted deficiencies of Barber. Strnad does not teach two receptacles. It merely shows a vertical shaft-in-bore arrangement that allows movement with respect to one another. Thus, Strnad fails to show any screw and slot combination that limits the movement of two

receptacles with respect to one another. While Strnad shows a pin extending through a slot in one part, it is for maintaining a non-rotational alignment of the two parts, as they are moved apart via the lock nut 110. Overall, in this case, Strnad fails to teach or suggest receptacles retracting or being spread apart with respect to each other using an elastomer, and the pin and slot combination of Strnad fails to remedy the deficiencies of Barber. Thus, Barber, in view of Strnad, fails to meet the limitations of claims 9 and 10.

Claims 11-13 stand rejected under 35 USC § 103(a) as being obvious in view of the combination of Barber (U.S. Patent No. 5,236,460) in view of Ferree (U.S. Patent No. 6,419,704). Applicants respectfully traverse this rejection.

Barber teaches the prosthesis with a filling material, as discussed above. But as the Office Action admits, Barber fails to teach this filling material is an elastomer. Thus, Barber, alone, fails to meet this limitation of claims 11 and 13. While Ferree was relied upon only for the teaching that a prosthetic body may be filled with an elastomer, Ferree does not address any other claim deficiencies. Thus, since claims 11-13 depend from claim 1, claims 11-13 should be patentable for the reasons noted above with respect to claim 1.

Claim 14 stands rejected under 35 USC § 103(a) as being obvious in view of the combination of Barber (U.S. Patent No. 5,236,460) in view of Ferree (U.S.



Patent No. 6,419,704) and Colleran (U.S. Patent No. 6,258,126). Applicants respectfully traverse this rejection.

Claim 14 has been amended to recite the surfaces of the body are generally planar and contact the elastomer when compressed. Claim 14 emphasizes the surfaces of the receptacles' walls are smooth and planar, so that when the receptacles are compressed together, their walls press against the elastomer generally uniformly across its entire surface. Colleran completely fails to teach this limitation. The walls in the Colleran device are far from planar and smooth. They contain a series of protrusions and depressions to provide a "high bearing surface contact area" so that the device can "mechanically mate[s]" with the elastomer. See Colleran, Figure 1 and column 4, lines 17-24.

Furthermore, Colleran is non-analogous art. To rely on a reference under 35 U.S.C. 103, the reference must be analogous prior art. Accordingly, the examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d

1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993); and *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1490 (Fed. Cir. 2003) (where the general scope of a reference is outside the pertinent field of endeavor, the reference may be considered analogous art if subject matter disclosed therein is relevant to the particular problem with which the inventor is involved).

Colleran is in an entirely different field of endeavor. Colleran is directed to a knee joint replacement prosthesis designed to reduce the tendency of developing wear debris during daily physical activities, where the knee is subjected to friction and continuous cycling and stress. See column 1, line 63, and column 2, lines 21-25. On the other hand, the device of the claimed invention is a spinal implant that functions as a pressure carrying placeholder, or temporary bridge, to ensure vertebral bodies will fuse at the implant location over time. Thus, the knee joint replacement of Colleran and spinal implant bridge are clearly in entirely different fields of endeavor.

Furthermore, Colleran is not reasonably pertinent to the particular problem with which the inventor was concerned. As discussed above, Colleran is directed to providing a knee joint prosthetic that discourages problematic wear debris from developing during daily physical activities, such as walking, where the knee joint is subjected to continuous cyclic stress. In contrast, the implant device of the present invention is directed to just providing a bridge between spinal vertebrae and facilitating natural bone development over this replacement location. The inventors were not focused on discouraging the development of wear debris over cyclic stress.

Furthermore, Colleran exclusively requires a hard elastomer is used in order to reproduce the mechanical properties of the joint it is designed to replace. See Colleran, column 4, lines 4-9. On the other hand, the claimed invention permits a liquid elastomer that may either remain liquid or harden. Thus, Colleran teaches away from this limitation of claim 14.

Thus, for these reasons, Colleran and is neither within the same field of Applicant's endeavor nor remotely pertinent to the particular problem with which the inventor was concerned. Overall, Colleran fails to remedy the deficiencies of Barber. Thus, for these reasons, Barber, in view of Ferree and Colleran, fail to teach or suggest the limitations of claim 14.

Claims 15-16 stand rejected under 35 USC § 103(a) as being obvious in view of the combination of Barber (U.S. Patent No. 5,236,460) in view of Ferree (U.S.

Patent No. 6,419,704) and Powell (U.S. Patent No. 4,517,844). Applicants respectfully traverse this rejection.

Claim 15 is directed to the implant, as discussed above, with a hollow air space remaining below the elastomer, between the elastomer and bottom wall of one of the receptacles. This space is left beneath the elastomer to increase the elasticity of the entire implant. Likewise, a spring element, or another type of inlay, could also be inserted in this space, in addition to or in lieu of the air pocket, to adjust or further increase the implant's overall elasticity.

Barber and Ferree fail to teach the limitations of claims 15 and 16, for the reasons discussed above, and also because they both, individually or in combination, fail to teach or suggest the elasticity of a prosthesis device can be changed by using a hollow air space or pocket.

Powell also fails to address the deficiencies of Barber and Ferree. Powell is non-analogous art. As discussed above, to rely on a reference as a basis for rejection of an applicant's invention, the reference "must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992); *Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767

(Fed. Cir. 1993); and *State Contracting & Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, 68 USPQ2d 1481, 1490 (Fed. Cir. 2003).

Here, Powell is non-analogous art.

Powell is in an entirely different field of endeavor. Powell is directed to an apparatus for removing undesirable resonance in a closed tubular fluid flow system. The device of Powell is used in a catheter transducer system used in electromanometry systems to permits hemodynamic pressure to be accurately measured and recorded. On the other hand, the device of the claimed invention is a spinal implant device. The system-device combination of Powell and the claimed implant device are clearly in entirely different fields of endeavor.

Furthermore, Powell is not reasonably pertinent to the particular problem with which the inventor was concerned. The inventor was concerned with improving the elasticity of the implant by providing this hollow space. Elasticity is a physical, mechanical property that describes the ability of a solid body to return to its original form after being strained. Here, the inventor provided this air space to increase the implant's ability to return to a specific shape after being subjected to a tensile or compression force. On the other hand, the air bubble of Powell is used for an entirely different purpose, to decrease, or dampen, the great latitude of natural frequency in a catheter-tubing transducer system.

Overall, Powell is neither within the same field of Applicant's endeavor nor remotely pertinent to the particular problem with which the inventor was concerned. Thus, Barber, in view of Ferree and Powell, fail to teach the limitations of claim 15.

Claim 18 depends from claim 1, and thus should be patentable for the reasons noted with respect to claim 1.

Claims 19-20 stand rejected under 35 USC § 103(a) as being obvious in view of Barber (U.S. Patent No. 5,236,460). Applicants respectfully traverse this rejection.

The Examiner has argued, generally, that it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the implant of metal, polymer, or a composite material in order to produce radiological shadows, because it is within the "general skill of a worker in the art to select a known material on the basis of suitability for the intended use as a matter of obvious design choice". *In re Leshin*, 125 USPQ 416. However, the holding of *In re Leshin* does not apply to the issue of obviousness with respect to claims 19 and 20 of the claimed invention. *In re Leshin* deals with lipstick container art, not the bone implant art. The mere selection of a known, commercially available plastic to make a lipstick container on the basis for suitability of housing a stick of lipstick would have been entirely obvious. But, when designing vertebral column implants, there

are more design constraints and considerations, and thus less design options for materials than there are for designing plastic lipstick containers. In this case, Barber fails to teach the limitations of claims 19 and 20 because it would not have been an obvious design choice to one of ordinary skill in the art to manufacture this vertebral column implant of metal, polymer, or a composite material.

Even if this were an obvious design choice, claims 19-20 depend from claim 1, and thus should be patentable for the reasons noted with respect to claim 1.

Also, in contrast to the present invention, the prosthesis of Barber is not for insertion into an opening of an intervertebral disc, but rather is only for a complete substitution of a vertebral body. Also, Barber fails to teach an implant that has a wedge shaped front end used to spread apart vertebral bodies before inserting the implant. Also, contrary to the claimed invention, the prosthesis of Barber is cylindrical, not bean-shaped, as required by amended claim 1.

Based on the arguments presented above, withdrawal of the rejection of all of the claims under 35 USC § 103(a) is respectfully requested.

**Conclusion**

If the Examiner believes that any additional minor formal matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to materially advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing [amendment and] remarks, Applicants respectfully submit that the present application, including claims 1-25, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

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Enclosure (Formal Drawings)